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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/186,810	11/05/1998	WENDA C. CARLYLE	1416.25US02	2290

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EXAMINER	
PREBILIC, PAUL B	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 10/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NT

Office Action Summary	Application No.	Applicant(s)	
	09/186,810	CARLYLE ET AL.	
	Examiner	Art Unit	
	Paul B. Prebilic	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4,8-10,13-15,28,29 and 33-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *28,29,33 and 41-44* is/are allowed.

6)☒ Claim(s) *1,3,4,8-10,13,15,34,35,38-40,45 and 46* is/are rejected.

7)☒ Claim(s) *14,36 and 37* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 46 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original support for the preclusion of a linker molecule as now claimed when the polypeptide growth factor is covalently bonded to the surface. In fact, the claim language even states that the crosslinking agent functions "to link the crosslinking agent directly with the polypeptide growth factor and the substrate"; see lines 3-6. Furthermore, the claimed invention does not appear to be enabled since a linker molecule is necessary for the invention to work as disclosed since the covalent attachment of crosslinking agent to the tissue requires attachment to some molecule of the tissue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 46 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 46, preclusion of a linker molecule is confusing and renders the claim language indefinite in that a molecule on the tissue

must link to the crosslinking agent to bond it thereto. Furthermore, the crosslinking molecule is used as or acts as a linker molecule so the preclusion of it is confusing. In this way, the claim language is internally inconsistent in that it both precludes "a linker molecule" and yet later states that the crosslinking agent functions "to link the crosslinking agent directly with the polypeptide growth factor and the substrate"; see lines 3-6.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 8, 10, 13, 15, 34, 35, and 38-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 9, 14, and 21 of copending Application No. 09/014,087. The present claims are obvious over the copending claims because the same embodiment is set forth herein such that the claims set read on each other and are clearly obvious in view of each other.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 8, 9, 15, and 45-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Cahalan et al (US 5,308,641). Cahalan anticipates the claim language where the natural tissue as claimed is the human or animal tissue of Cahalan, and the crosslinking agents as claimed are the combination of the crosslinking agent of dialdehydes and the polyalkylimine of Cahalan (see column 6, lines 8-51 where the polyalkylimine and crosslinking agent are used together to link the biomolecule to the solid surface; the solid surface can be a natural tissue). In other words, the molecules of an aldehyde and polyalkylimine are joined to form a crosslinking agent that attaches polypeptide growth factor to the substrate; see especially column 4, lines 20-62, the abstract, and column 6, lines 8-51. Cahalan discloses that one purpose of the surface treatment is to "promote the attachment and growth of a normal cell layer"; see column 1, lines 33-43. For this reason, it stimulates the "association of viable cells with the substrate" as claimed.

With regard to claim 8, the xenograft tissue as claimed is clearly implied by the animal tissue disclosed by Cahalan such that this claim language is considered fully met thereby; see column 4, lines 32-33.

Regarding claim 15, Applicants are directed to column 4, lines 36-43 where some of the same biomedical devices are disclosed as substrates.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cahalan et al (US 5,308,641) in view of Goldstein (US 5,613,982). Cahalan discloses medical devices/implants where the crosslinking agent glutaraldehyde attaches the growth factor biomolecule and to the substrate-spacer. Cahalan's solid surface can be made of human or animal tissues (see column 4, lines 32-33), but Cahalan lacks the types of tissues claimed.

However, Goldstein teaches that it was known to make similar medical devices/implants out or heart valves, pericardial tissue and the like; see especially column 3, lines 14-24.

Therefore, it is the Examiner's position that it would have been obvious to use heart valve or pericardial tissue for Cahalan's solid surface in order to reduce the risk of disease transmission and cost over using human tissue. Furthermore, it would have been obvious to use these tissues for the same reasons that Goldstein desires the same.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cahalan et al in view of Bayne et al (EP 0476983).

With regard to claim 13, Cahalan fails to disclose the use of VEGF as claimed even though it discloses utilizing many other growth factors therewith. Bayne teaches that it was known to use VEGF as the growth factor in a similar fashion within the same art; see the see page 8, lines 14-26.

Therefore, it is the Examiner's position that it would have been obvious to an ordinary artisan to use VEGF as the growth factor of Cahalan so that the implant could be successfully implanted in vascular regions of the body.

Allowable Subject Matter

Claims 28, 29, 33, and 41-44 are allowed over the prior art of record.

Claims 14, 36, and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are not considered persuasive.

In response to the argument traversing the Section 112 rejections of claim 46 that the preclusion is acceptable because of different embodiments, the Examiner asserts that the crosslinking agent of the present invention is a type of linker molecule because it functions to link the biomolecule to the surface. The claim even states this; see lines 3 to 6 of claim 46. For this reason, preclusion of a linker molecule when

covalent bonds are formed does not have original support. Furthermore, the claim is indefinite because it is internally inconsistent. It is noted that the Applicant refers to the specification on pages 14 to 15 for the contention that separate embodiments are disclosed. However, the disclosed embodiments do not include covalent bonding of the growth factor to natural tissue because the tissue therein is already crosslinked and does not state that a covalent bond is formed; see page 14, line 3 to page 15, line 6 and see MPEP 2173.05 (i), second paragraph thereof that is incorporated herein by reference.

In response to the traversal of the Cahalan rejections that the Examiner has taken a impermissibly broad interpretation thereof, the Examiner respectfully disagrees and asserts that since the two molecules of polyalkylimine and aldehyde are used together to surface bond the biomolecule, it is permissible to call the molecules together crosslinking agents. This is due to the fact that these molecules function to crosslink the surface and attach the biomolecule so they together function as a crosslinking agent. For this reason, the Examiner has merely given the claim language it broadest reasonable interpretation.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Prebilic
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Art Unit 3738